

WHAT IS CLAIMED IS:

S. 1 1. A method of inducing an immune response by administration of a recombinant immunogen expressed from a plasmid which comprises in operable linkage:

- 5 a) an origin of replication;
- b) a promoter;
- c) DNA sequence encoding a fusion protein of an antigen of interest fused in frame to the A2 subunit of a type II heat-labile enterotoxin; and
- 10 d) DNA sequence encoding subunit B of type II heat-labile enterotoxin for coexpression with the fusion protein of said antigen of interest to facilitate assembly of a chimeric protein.

15 2. The method of claim 1, wherein said antigen of interest is salivary binding protein (SBR) from *Streptococcus mutans* surface protein (Ag I/II).

3. The method of claim 1, wherein said type II heat-labile enterotoxin is selected from the group consisting of *E. coli* heat-labile type IIa toxin and *E. coli* heat-labile type IIb toxin.

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~~4. The method of claim 1, wherein said plasmid is~~

~~pVAR9.~~

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~~5. The method of claim 1, wherein said plasmid is~~

~~pSBR-LT-IIbA2/B.~~

6. The method of claim 1, wherein said immunogen is administered by a route selected from the group consisting of orally, intranasally, intrarectally, intravaginally, intramuscularly, transcutaneously and subcutaneously.

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~~7. The method of claim 1, wherein said immune response results in the production of antibodies to the antigen~~

sequence in a bodily fluid selected from the group consisting of saliva, intestinal secretions, respiratory secretions, genital secretions, tears, milk and blood.

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8. The method of claim 1, wherein said immune response is selected from the group consisting of development of antigen-specific T cells in the circulation and tissues, the development of cytotoxic T cells and immunological tolerance to the antigen sequence.

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9. A method of inducing a B7-dependent immune response by administration of a recombinant immunogen expressed from a plasmid which comprises in operable linkage:

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- a) an origin of replication;
- b) a promoter;
- c) DNA sequence encoding a fusion protein of an antigen of interest fused in frame to the A2 subunit of cholera toxin; and

d) DNA sequence encoding subunit B of cholera toxin for coexpression with the fusion protein of said antigen of interest to facilitate assembly of a chimeric protein.

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10. The method of claim 9, wherein said antigen of interest is salivary binding protein (SBR) from *Streptococcus mutans* surface protein (Ag I/II).

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11. The method of claim 9, wherein said immunogen is administered by a route selected from the group consisting of orally, intranasally, intrarectally, intravaginally, intramuscularly, transcutaneously and subcutaneously.

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12. The method of claim 9, wherein said immune response results in the production of antibodies to the antigen sequence in a bodily fluid selected from the group consisting of saliva, intestinal secretions, respiratory secretions, genital secretions, tears, milk and blood.

13. The method of claim 9, wherein said immune response results in enhanced IgG1 production to the antigen sequence in a bodily fluid selected from the group consisting of saliva, intestinal secretions, respiratory secretions, genital secretions, tears, milk and blood.

14. The method of claim 9, wherein said immune response is selected from the group consisting of development of antigen-specific T cells in the circulation and tissues, the development of cytotoxic T cells and immunological tolerance to the antigen sequence.

15. The method of claim 9, wherein said B7-dependent immune response is selected from the group consisting of induction of B7-2 expression on antigen presenting cells, B7-2-mediated co-stimulation of T cell proliferation, enhanced IgG1 secretion and induction of Th2 immune responses.

16. The method of claim 15, wherein said antigen presenting cell is selected from the group consisting of monocytes, macrophages, dendritic cells and B cell.

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17. A method of reducing CD40L expression on CD4⁺ T cells by administration of a recombinant immunogen expressed from a plasmid which comprises in operable linkage:

a) an origin of replication;

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b) a promoter;

c) DNA sequence encoding a fusion protein of an antigen of interest fused in frame to the A2 subunit of cholera toxin; and

d) DNA sequence encoding subunit B of cholera toxin for coexpression with the fusion protein of said antigen of interest to facilitate assembly of a chimeric protein.

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18. The method of claim 17, wherein said antigen of interest is salivary binding protein (SBR) from *Streptococcus mutans* surface protein (Ag I/II).

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19. The method of claim 17, wherein said immunogen is administered by a route selected from the group consisting of orally, intranasally, intrarectally, intravaginally, intramuscularly, transcutaneously and subcutaneously.

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20. A method of reducing TNF- α or IL-12 secretion in an individual by administration of a recombinant immunogen expressed from a plasmid which comprises in operable linkage:

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a) an origin of replication;

b) a promoter;

c) DNA sequence encoding a fusion protein of an antigen of interest fused in frame to the A2 subunit of cholera toxin; and

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d) DNA sequence encoding subunit B of cholera toxin for coexpression with the fusion protein of said antigen of interest to facilitate assembly of a chimeric protein.

21. The method of claim 20, wherein said antigen of interest is salivary binding protein (SBR) from *Streptococcus mutans* surface protein (Ag I/II).

22. The method of claim 20, wherein said immunogen is administered by a route selected from the group consisting of orally, intranasally, intrarectally, intravaginally, intramuscularly, transcutaneously and subcutaneously.

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23. The method of claim 20, wherein said TNF- α or IL-12 is secreted from cells selected from the group consisting of human peripheral blood mononuclear cells, monocytes, macrophages and dendritic cells.

24. A method of increasing Th1 response and cell-mediated immunity by administration of a recombinant immunogen expressed from a plasmid which comprises in operable linkage:

- a) an origin of replication;
- b) a promoter;
- c) DNA sequence encoding a fusion protein an antigen of interest fused in frame to the A2 subunit of a type II heat-labile enterotoxin; and

d) DNA sequence encoding subunit B of type II heat-labile enterotoxin for coexpression with the fusion protein of said antigen of interest to facilitate assembly of a chimeric protein.

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25. The method of claim 24, wherein said antigen of interest is salivary binding protein (SBR) from *Streptococcus mutans* surface protein (Ag I/II).

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26. The method of claim 24, wherein said immunogen is administered by a route selected from the group consisting of orally, intranasally, intrarectally, intravaginally, intramuscularly, transcutaneously and subcutaneously.

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Sub 23 27. A method of increasing Th1 response and cell-mediated immunity by administration of a recombinant immunogen expressed from a plasmid which comprises in operable linkage:

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- a) an origin of replication;
- b) a promoter;

c) DNA sequence encoding a fusion protein an antigen of interest fused in frame to the A2 subunit of a *E. coli* heat-labile type IIa or type IIb toxin; and

5 d) DNA sequence encoding subunit B of type II heat-labile enterotoxin for coexpression with the fusion protein of said antigen of interest to facilitate assembly of a chimeric protein.

28. The method of claim 27, wherein said antigen of interest is salivary binding protein (SBR) from *Streptococcus mutans*
10 surface protein (Ag I/II).

29. The method of claim 27, wherein said immunogen is administered by a route selected from the group consisting of orally, intranasally, intrarectally, intravaginally, intramuscularly,
15 transcutaneously and subcutaneously.